

Assessment of multiple drugs of abuse simultaneously using Toxplex Urine Array to confirm clinical performance

Submission date 29/06/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 08/07/2026	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 11/08/2026	Condition category Other	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Drug abuse in any form gives rise to serious negative consequences not only for the abuser, by devastating their mental and physical health, but also for the whole of society. It is an indirect and direct cause of many crimes and also in the spread of diseases. It is very costly, with costs related to crime, medical care, treatment and welfare programs for addicted individuals and wasted working hours. Urine drug testing can provide a tool for detecting users and for monitoring the compliance of subjects in recovery programs. Randox has developed a sensitive, multidrug approach for detecting 23 drugs as well as a marker for sample dilution in urine samples as an aid to diagnosis. The study aims to test the performance of the Randox Evidence MultiSTAT Toxplex Urine Array as a preliminary testing device for clinical use in the measurement of drugs of abuse.

Who can participate?

Persons aged 18 years and over who have consented for their leftover urine sample being used for Research and Development

What does the study involve?

The study will use de-identified leftover pooled residual samples received at Randox Clinical Laboratory Services (RCLS) during routine diagnostic testing. Results using the Evidence MultiSTAT Toxplex Urine Array will be compared to another preliminary testing device to demonstrate clinical performance. In addition, a number of known positives sourced from the US will be run blinded as part of the study to demonstrate performance for both positive and negative samples. Positive samples detected will be confirmed using chromatography methods.

What are the possible benefits and risks of participating?

Although no clinical decisions will be made on the results of this study, participants will be contributing to the wider scientific community by participating in the assessment of a multiplex test that can detect large numbers of drugs of abuse simultaneously, which aids in determining

which drug or combination of drugs has been administered. This screening device aids in determining the best treatment pathway. As the study is being conducted with leftover de-identified clinical samples, there are no risks to the participants.

Where is the study run from?

Radox Clinical Laboratory Services (RCLS), Northern Ireland

When is the study starting, and how long is it expected to run for?

July 2026 to August 2026

Who is Funding the Study?

Radox Laboratories Ltd, Northern Ireland

Who is the main contact?

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Contact information

Type(s)

Principal investigator

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Additional identifiers

Study information

Scientific Title

Evidence MultiSTAT DOA Toxplex Urine Array clinical performance study

Acronym

ToxPlex Urn CPS

Study objectives

The clinical performance study is intended to demonstrate the clinical performance of the Evidence MultiSTAT Drugs of Abuse (DOA) Toxplex Urine Array in a clinical laboratory setting with trained laboratory personnel.

The Evidence MultiSTAT DOA ToxPlex Urine Array are in vitro diagnostic tests for the semi-quantitative determination of the parent molecule and metabolites of drugs in human urine. The Evidence MultiSTAT Drugs of Abuse (DOA) Toxplex Urine Array in a clinical laboratory setting with trained laboratory personnel.

The Evidence MultiSTAT DOA ToxPlex Urine Array detects the following drugs at the specified cut-off:

1. Methamphetamine (500 ng/ml)
2. Methylenedioxy-methamphetamine (MDMA) (500 ng/ml)
3. Amphetamine (500 ng/ml)
4. Tricyclic antidepressants (500 ng/ml)
5. Noroxycodone (100 ng/ml)
6. Opiate (300 ng/ml)
7. 6-Acetylmorphine (6-MAM) (10 ng/ml)
8. Benzodiazepines 1 (200 ng/ml)
9. Benzodiazepines 2 (200 ng/ml)
10. Barbiturates (200 ng/ml)
11. Cannabinoids (50 ng/ml)
12. Methadone (300 ng/ml)
13. Benzoyllecgonine/cocaine (150 ng/ml)
14. Tramadol (200 ng/ml)
15. Fentanyl (2 ng/ml)
16. Buprenorphine (5 ng/ml)
17. Phencyclidine (PCP) (25 ng/ml)
18. Zolpidem (20 ng/ml)
19. Ketamine (300 ng/ml)
20. Pregabalin (1000 ng/ml)
21. Adulterant Check (20 mg/dl)
22. Ethyl glucuronide (ETG) (1000 ng/ml)
23. Acetaminophen (50 µg/ml)
24. Salicylates (50 µg/ml)

The test system will provide a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result.

Ethics approval required

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Ethics approval(s)

Approved 08/07/2026, London - Dulwich Research Ethics Committee (2 Redman Place Stratford, London, E20 1JO, United Kingdom; +44 (0)207 104 8290; dulwich.rec@hra.nhs.uk), ref: 26/LO/0540

Primary study design

Observational

Secondary study design

Single-center observational study

Study type(s)

Health condition(s) or problem(s) studied

Drugs of abuse use

Interventions

An observational study will take place where 100 left-over consented pooled samples (suspected negatives) will be assessed on the Evidence MultiSTAT Toxplex Urine Array EV4505 to test for the presence of parent molecules and metabolites of drugs in the human urine sample. Negative samples will be assessed on another preliminary testing device, Evidence Investigator Drugs of Abuse Array EV3512.

An additional 30 blinded positives will also be assessed for the study, which have been sourced from the US with an IRB-approved waiver of consent in place.

Positive samples will be confirmed by confirmatory methods such as gas chromatography-mass spectrometry (GC/MS) and liquid chromatography-tandem mass spectrometry (LC/MS/MS).

Study endpoints will include the correlation of results with another preliminary testing method (Randox Evidence Investigator Drugs of Abuse Array EV3512) for negative samples and against confirmatory methods such as GC/MS or LC/MS/MS for positive samples with results reviewed to determine the percentage agreement, diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value and likelihood ratio.

Intervention Type

Other

Primary outcome(s)

1. Diagnostic sensitivity of the Evidence MultiSTAT Toxplex Urine Array compared with the reference method measured using $100 \times [\text{True Positive}/(\text{True Positive} + \text{False Negative})]$ at a single timepoint
2. Diagnostic specificity of the Evidence MultiSTAT Toxplex Urine Array compared with the reference method measured using $100 \times [\text{True Negative}/(\text{False Positive} + \text{True Negative})]$ at a single timepoint

3. Overall percentage agreement measured using $[(\text{True Positive} + \text{True Negative}) / \text{Total number of Samples}] \times 100$ at a single timepoint

True Positive (TP) = Number of samples positive by test method and reference method

True Negative (TN) = Number of samples negative by test method and reference method

False Positive (FP) = Number of samples positive by test method but negative by reference method

False Negative (FN) = Number of samples negative by test method but positive by reference method

Key secondary outcome(s)

There are no secondary outcomes

Completion date

31/08/2026

Eligibility

Key inclusion criteria

1. Person aged ≥ 18 years
2. Person consented for leftover urine sample being used for Research and Development

Healthy volunteers allowed

Yes

Age group

Mixed

Lower age limit

18 Years

Upper age limit

110 Years

Sex

All

Total final enrolment

130

Key exclusion criteria

1. Person aged < 18 years
2. Person who have not consented for left over urine sample being used for Research and Development

Date of first enrolment

01/07/2026

Date of final enrolment

31/07/2026

Locations

Countries of recruitment

United Kingdom

Northern Ireland

Ireland

Study participating centre

Randox Clinical Laboratory Services

Randox Science Park

30 Randalstown Road

Antrim

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Sponsor information

Organisation

Randox (United Kingdom)

ROR

<https://ror.org/04cte7x29>

Funder(s)

Funder type

Funder Name

Randox Laboratories Limited

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available